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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,895	01/07/1999	MICHAEL ROSENBLUM	D6205	8983

27851 7590 11/23/2001

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/226,895

Applicant(s)
Rosenblum et al

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jul 9, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s):

none

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:

see attached

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: none

Claim(s) objected to: none

Claim(s) rejected: 1, 5-9, and 11

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. ☐ Other: _____

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1. The rejection of claims 1, 7-9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Mehta et al (Proceedings of the American Association for Cancer Research, 1997, Vol. 38, p. 88) in view of Flavell et al (Cancer Research, 1997, Vol. 57, pp. 4824-4829) is maintained for reasons of record.

2. The rejection of claims 1, 5-9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Mehta et al, 1997 and Flavell et al and Mehta et al (Proceeding of the American society for Cancer Research, 1994, Vol. 35, p. 92) is maintained for reasons of record.


3. Applicant argues that without actually attempting the method of upregulation of CD38 by retinoids, followed by the administration of an anti-CD38 immunotoxin, one of skill in the art would not be able to determine if the anti-CD38 immunotoxin would be effective as the sole administered immunotoxin. Applicant states that it is possible that the anti-CD38 immunotoxin would have remained ineffective against leukemia cells. Applicant further argues that Flavell et al teaches away from the instant claims by teaching the administration of the anti-CD38 immunotoxin as useful only in a cocktail of several immunotoxins. This has been considered but not found persuasive. Flavell et al teach that the anti-CD38 immunotoxin when administered as the sole immunotoxin, although not capable of killing all of the B-cell lymphoma cells, significantly prolonged the life of experimental animals carrying said cells (abstract, lines 5-6). Therefore, Flavell et al teach that the anti-CD38 immunotoxin had some effectiveness against the B-cell lymphoma in vivo. Flavell et al further teach that the combination of immunotoxins, anti-CD19, anti-CD22 and anti-CD38, was the most effective at killing the lymphoma cells as it was to be expected that not all the tumor cells would express all the targeted antigens on the same cell, but that it were more likely that the tumor cells would express at least one of the antigens (p. 4824, Introduction section) on every cell. Mehta et al teach that retinoic acid was effective at upregulating CD38 in leukemia cell lines. Mehta et al further teach that an anti-CD38 gelonin

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immunotoxin was much more effective at killing retinoic acid treated leukemia cell lines than leukemia cell lines not treated with retinoic acid. Mehta et al further suggests that this method of upregulating CD38 antigen, followed by administration of an anti-CD 38 immunotoxin would be applicable to clinical treatment of leukemias. By this statement Mehta et al provides the motivation to treat leukemia in patients by administration of retinoic acid followed by an anti-CD38 immunotoxin. Thus, one of skill in the art would be motivated to combine Flavell et al and Mehta et al in order to overcome the deficiency of Flavell et al with respect to the lack of a CD38 target on every leukemia cell. As the anti-CD38 immunotoxin demonstrated some effectiveness in the experiments of Flavell et al, one of skill in the art would expect that the anti-CD38 would be more effective against leukemia cells treated with retinoids in a patient, as there will be more CD38 available on the tumor cells, and the probability that an individual tumor cell would express CD38 would be increased.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 19, 2001


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